

### REMARKS/ARGUMENTS

This is intended as a full and complete response to the Office Action dated August 10, 2007. Please reconsider the claims pending in the application for reasons discussed below.

### DISPOSITION OF CLAIMS

Claims 1 and 4-10 are pending in this application. Claim 11 has been canceled in view of a previous restriction requirement.

### REJECTIONS UNDER 35 U.S.C. §103

Claims 1 and 4-10 stand rejected under 35 U.S.C. § 103 as being unpatentable over Theeuwes et al. (U.S. Patent No. 4058122). This rejection is respectfully traversed.

The Examiner asserts that "while Theeuwes does not explicitly teach the instantly claimed percentage of water-soluble polymers (of at least 80% by weight), generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical." Citing *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA, 1955), the Examiner further states that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." The Examiner further asserts that Applicants have not demonstrated any superior or unexpected results that accrue from the claimed weight amount of water-soluble polymer.

The superior result that accrues from the claimed percentage of water-soluble polymer(s) in claims 1 and 4-10 is that the internal lamina recited in claims 1 and 4-10 dissolves and forms a gelatinous layer which lubricates the semipermeable wall and substantially prevents the semipermeable wall from cracking while the dosage form is dispensing the drug. The general conditions of claims 1 and 4-10 include an internal lamina made substantially of water soluble polymer(s) and which breaks down to form a

gelatinous layer when hydrated and while the dosage form is dispensing drug. This general condition is not disclosed or suggested by Theeuwes et al.

Theeuwes et al. disclose and teach an internal semipermeable lamina that maintains its physical and chemical integrity while the dosage form is dispensing drug. Theeuwes et al. disclose that the phrase "maintains its physical and chemical integrity" means that the laminated wall keeps its general constitution and general preselected design and shape in the environment of use and in the presence of agent during the period of agent release even though the system may be flexible and resilient. See, col. 6, lines 61-66. By this definition, the amount of water soluble polymer(s) that can be included in the internal semipermeable lamina is necessarily limited to the amount which would not result in a lamina that loses its general constitution and general preselected design and shape during the period of agent release. In other words, Theeuwes et al. define the water soluble polymer content of the internal semipermeable lamina though specification of the properties of the internal semipermeable lamina. In particular, the internal semipermeable lamina disclosed in Theeuwes et al. cannot be made substantially of water soluble polymer(s). In the examples disclosed in Theeuwes et al., the internal semipermeable lamina has polyethylene oxide in an amount of 20% by weight or less, typically around 10% by weight. Such a small amount of water soluble polymer in a lamina while satisfying the requirements of the internal semipermeable lamina described by Theeuwes et al. would not produce an internal lamina as recited in claims 1 and 4-10.

From the foregoing, not only does Theeuwes et al. fail to disclose or suggest an internal lamina as recited in claims 1 and 4-10, Theeuwes et al. also teach away from an internal lamina as recited in claims 1 and 4-10. Further, an internal lamina as recited in claims 1 and 4-10 delivers superior results in that it prevents or substantially prevents the semipermeable wall from cracking while dispensing drug, thereby preventing system malfunction. Withdrawal of the rejection of claims 1 and 4-10 in view of Theeuwes et al. is respectfully requested.

## CONCLUSION

Applicant believes that this paper is fully responsive to the Office Action dated August 10, 2007, and respectfully requests that a timely Notice of Allowance be issued in this case. A call to the undersigned is encouraged if the Examiner believes that a telephone conference would advance prosecution of this application.

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Respectfully submitted,  
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